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In The
Supreme Court of the United States

Wyeth,
Petitioner,
v.
Diana Levine,
Respondent.

On Writ of Certiorari to the Supreme Court of Vermont

AMICUS CURIAE BRIEF OF THE CITIZENS COMMISSION ON HUMAN RIGHTS

IN SUPPORT OF RESPONDENT

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I – INTEREST OF AMICUS

Amicus Citizens Commission on Human Rights [1] (CCHR) is a non-profit, public benefit organization dedicated to investigating and exposing psychiatric violations of human rights.

CCHR's members include prominent doctors, lawyers, artists, educators, civil and human rights representatives and professionals who see it as their duty to expose and help abolish physically damaging practices in the field of mental healing. With about 250 chapters in more than 30 countries, CCHR seeks to accomplish these stated aims with like-minded individuals and groups, including politicians, teachers, healthcare professionals, government, law enforcement officers and the media.

CCHR's expertise lies in part, in the investigation and study of the misuse and unethical use of psychotropic drugs. CCHR's study includes the means by which questionable, unreliable and unscientific diagnosis and labeling of citizens as mentally ill has created an apparent epidemic of mental "illnesses," resulting in the prescription of often dangerous drugs. On behalf of its chapters, its thousands of members and in the interest of persons whose rights and freedoms will not otherwise be heard,

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[1] Letters from the parties consenting to the filing of amicus briefs have been lodged with the Clerk of the Court. In accordance with Rule 37.6, amicus states that no counsel for any party authored or participated in any manner in this brief. No entity or person, aside from amicus, made any monetary contribution to the preparation or submission of this brief.

CCHR offers a different perspective than those of the parties or other amici.

II - SUMMARY OF ARGUMENT

The central premise of the Petitioner's argument and that of other amici supporting Petitioner, is that the Food and Drug Administration (FDA) is composed of supposedly neutral experts and that it is the sole entity competent to make determinations regarding the safety and efficacy of drugs on behalf of health care practitioners, consumers and plaintiffs who have been injured by pharmaceutical companies' products.

However, substantial public record information indicates that this presumption of the FDA's singular expertise is neither accurate nor warranted. And, upon this inaccurate presumption, the health and the lives of literally millions of persons hang in the balance.

In reality, the FDA has become subverted by the industries it regulates. It is overtly attacked by whistleblowers, Congress and watchdog groups for incompetence and dishonesty. The FDA has failed to perform its duty of preventing the distribution of dangerous drugs or of adequately warning the public of the dangers of drugs once they are known. In the past several years, the Commissioner and executives of the FDA have been called on the carpet before angry Congressional committees to explain why they ordered FDA scientists not to reveal the dangers of some medications and why the FDA permits persons with blatant conflicts of interest to hold positions of great responsibility over the approval of drugs. Because the FDA has been unable to maintain its own internal ethical standards, it has been the subject of recent legislative attempts to restore order within its

ranks. As Senator Charles Grassley stated on September 20, 2006, the FDA "has lost its way and 'sold out' to the industries it is charged to regulate." [2]

Indeed, conflicts of interest by the Advisory Committee members appointed by the FDA to investigate and approve medications for distribution, have become endemic.[3] Advisory Committee members frequently receive funds from the pharmaceutical companies which manufacture the drugs upon which the committee makes determinations of safety and efficacy. The FDA is well aware of the conflicts of interest of its appointees and routinely waives the conflicts as a matter of standard practice. As a result, excessively dangerous drugs are frequently approved by the agency for general consumption and sale.

Petitioner's position that FDA infallibility trumps all other inquiry into the safety of drugs is a fiction benefiting only pharmaceutical companies. Adoption of that position could prevent millions of victims from acquiring recourse and compensation for their injuries, and would eliminate the important checks and balances necessary to restrain large corporations from seeking profit by destroying the health, happiness and even the

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[2] Press release of Senator Charles Grassley, September 20, 2006.

[3] The GAO's investigation into the FDA led to published findings in 2006 that determined that when safety experts made recommendations to the FDA they went into a "black hole or abyss," the FDA had barred experts from testifying publicly and the "FDA lacks a clear and effective process for making decisions about, and providing management oversight of, postmarket drug safety issues." Ref: "Congress should strengthen FDA, report finds," Washington Post.com, 24 Apr. 2006; "FDA ill on tracking pills," *USA Today*, 26 Apr. 2006

lives of our citizens.

III - ARGUMENT

A. FDA Conflicts of Interest Result in Questionable Determinations of Drug Safety and Efficacy

Petitioner's central thesis is that the civil verdicts of "lay jurors" regarding drug safety "would displace FDA's expert judgment" and thereby cause "second guessing" of FDA determinations regarding the safety and efficacy of a given drug. (Petitioner's Brief at 28.) Petitioner characterizes such FDA deliberations as having an omnipotent character and argues it should not be subject to question or doubt by those who must rely upon the FDA's determinations: "FDA approved drug labeling 'communicates to health care practitioners the agency's formal authoritative conclusions regarding the conditions under which the product can be used safely and effectively." (Opening Brief at 8.)

But blind faith in the infallibility – or even the good intentions – of those who make determinations on drug safety, is simply not warranted for the reasons that follow.

B. FDA Advisory Committee "Experts" Are Not Independent. Most Have Substantial Conflicts of Interest.

If the approval of a drug or class of drugs is controversial, or public safety issues are debated, the FDA typically consults a scientific Advisory Committee whose members are selected and paid by the FDA but are not FDA employees. [4] The Agency explains:

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[4] "FDA Advisory Committees: Does Approval Mean Safety?" Report from National Research Center for Women and Families; "Guidance for

> Advisory committees provide the FDA with independent opinions and recommendations from outside experts on applications to market new drugs, and on FDA policies. The marketing applications include data to show the safety and effectiveness of human drugs.... Based on this information, advisory committees may recommend approval or disapproval of a drug's marketing application. FDA generally follows an advisory committee's recommendation ..." [5]

Yet, the public record demonstrates that the FDA and its Advisory Committees typically have conflicts of interest by virtue of payments from pharmaceutical companies to the members of the committees approving the drugs. This circumstance is both condoned and even approved by the FDA. Advisory Committees composed of conflicted members have made some stellar errors of judgment, certainly resulting in the loss of many lives. Two examples out of many demonstrate the result of the FDA's refusal to inform the public of dangerous attributes of certain drugs where the Agency's "experts" were conflicted.

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the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers," U.S. Food and Drug Administration, Oct. 2007.

[5] http://www.fda.gov/cder/audiences/acspage/

1. The FDA's Refusal to Warn of Suicide and Violence Caused by Antidepressants

It is now widely accepted that the class of antidepressant drugs known as "selective serotonin reuptake inhibitors" or "SSRI" drugs causes suicidal ideation, has resulted in many suicides and has resulted in many acts of violence, self mutilation and homicide. The FDA has recently issued "black box warnings" that children and young adults are particularly susceptible to the inducement of suicide and violence by SSRI drugs.[6] But the FDA and its Advisory Committee investigating SSRIs refused to acknowledge these harms for nearly 20 years, while thousands died and many lawsuits were filed against pharmaceutical companies for damages caused by this class of drugs.

In 1987, a new drug was approved by the FDA that was to have a dramatic influence on life in the western world: the antidepressant Prozac, representing the first in what became a highly profitable line of SSRI drugs. Almost immediately, numerous reports of suicidality, violence, and hostility were associated with persons taking the drug. By 1991, Prozac had the highest number of adverse drug reaction reports of any other drug in the FDA's Adverse Event Reporting System (AERS): 402 suicide attempts, 60 deaths and over 17,000 other adverse reactions. [7] And, the FDA admitted, only between 1% and

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[6] Labeling Change Request Letter for Antidepressant Medications – FDA Letter, 15 Oct. 2004; "FDA orders strong 'black box' warnings on antidepressants used by children," *Associated Press Worldstream*, 15 Oct. 2004.

[7] May 30, 1991 memo from Alan Gelberg, Acting Chief,

10% of the actual adverse events are even reported, so the actual figures could be ten times as high. [8]

In the case of Prozac, the FDA essentially ignored the Adverse Reports in its files and kept the drug on the market, resulting in other drug companies quickly copying and marketing this lucrative compound. After 4 years of inaction in policing antidepressant fatalities and attempted suicides, the FDA agreed in September 1991 to hold public hearings on SSRI drugs before its Psychopharmalogical Drugs Advisory Committee (PDAC), based on a petition from Amicus Citizens Commission on Human Rights and pressure from victims and Congress.

It would seem astonishing that the FDA would condone much less *select* persons with blatant conflicts of interests with pharmaceutical companies to sit in judgment on Advisory Committees making determinations on life and death issues regarding drug safety. But the practice was and is commonplace in this agency. The FDA's justification for inviting non-governmental employees with conflicts to vote on approval of questionable drugs, is whether the "need for the individual's services outweighs the potential for a conflict

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Surveillance & Data Processing Branch of the Center for Drug Evaluation and Research of the FDA.

[8] "Use of Anti-Malarial Drug Lariam Previously Used by Peace Corps Veterans Linked to Mental Disorders, Suicide, (Part I)," *Insight Magazine*, 21 May 2002; Marilyn Elias, "New Antipsychotic Drugs Carry Risks for Children," *USA Today*, 2 May 2006; "UK Parliament Report Re: Pharma Influence / US Regulators Comatose as 258 Fatal Suicides Linked to Neurontin," Alliance for Human Research Protection, 6 April 2005.

of interest created by the financial interest involved." [9] However, appointment to an FDA Advisory Committee carries the status of a "special employee" of the agency. Thus, the presence of a conflict of interest in performing this official duty constitutes a federal crime, and the FDA routinely provides a "waiver" of the conflict, thus shielding the conflicted member from criminal prosecution.

Although the FDA's Division of Drug Information does not make records available to the public regarding the numbers of criminal prosecution waivers provided on a yearly or ongoing basis, the watchdog group, Public Citizen, undertook a study of records from 221 FDA Advisory Committees. It found that in 73% of the Advisory Committees, at least one member had an acknowledged financial conflict of interest, the most common of which were consulting agreements, contracts, grants and investments. The study also found that in 14% of the Committees, *three-fourths* or more of the members had conflicts, and that in 22% of the Committees *over half* of the members had financial conflicts.[10] Moreover, such conflicts rarely resulted in disqualification of the member, (*id.*), as the FDA is generous in waiving responsibility for such conflicts.

The 1991 PDAC was singularly conflicted even with

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[9] "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees," U.S. Food and Drug Administration, Oct. 2007.

[10] Peter Lurie, "Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings." *Journal of the American Medical Association*, April 26, 2006.

these loose rules. Five of the ten Advisory Committee members had acknowledged financial interests in the pharmaceutical companies manufacturing the lucrative SSRI drugs at issue in the hearings. Each conflicted member requested and was granted a waiver of criminal prosecution.[11] Not revealed by the FDA was that two of the remaining five "non-conflicted" voting members of the Committee both held positions with the National Alliance for Research on Schizophrenia and Depression, funded by Eli Lilly – the manufacturer of Prozac, and one had received a grant of "less than $100,000" from the pharmaceutical-company funded National Alliance for Research on Schizophrenia and Depression, prior to the meeting. [12] Thus, seven of the ten PDAC members had financial conflicts of interest.

The FDA also invited six unpaid "guests" to participate in the Advisory Committee as non-voting "consultants," three of whom, the FDA admitted, also had conflicts of interest with drug companies.[13]

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[11] James Claghorn, Keh-Ming Lin, Jeffrey Lieberman, Robert Hamer and David Dunner. Statement of Michael Bernstein, Executive Secretary of the Pharmacologic Drugs Advisory Committee, September 20, 1991.

[12] Drs. Nina Scooler and Carol Tamminga. www.utsouthn western.edu/findfac/personal/0,2358,58406,00.html. At a later meeting of the PDAC, called to address the use of Prozac for the new purported illness "premenstrual dysphoric disorder," the FDA formally conceded Dr. Tamminga had conflicts but was permitted to chair the Committee because the FDA deemed that her "participation outweighs the concern that the integrity of the agency's program and operations be questioned."

[13] The other conflicted members were John Mann, Stewart Montgomery and Martin Teicher. Statement of Michael Bernstein, Executive Secretary of the Pharmacologic Drugs

At the 1991 PDAC meeting, dozens of victims and their doctors gave heart rending testimony of attempted suicides, completed suicides, murders and destruction caused by antidepressants. The Committee had thousands of adverse reaction reports, including reports of at least 60 deaths. At the culmination of the testimony, the Committee nevertheless voted that there was no "credible" evidence to support the conclusion that antidepressant drugs caused the emergence of suicidality and other violent behavior.[14] Unsurprisingly, each of the seven Advisory Committee members with financial ties to pharmaceutical companies voted that no warning should be given to doctors and users of these dangerous antidepressants. The FDA adopted the Advisory Committee's recommendations, as it normally does, and declined to issue any public warning.

To the public, it was promoted that the FDA had thoroughly evaluated the issue, and the SSRI drugs were entirely safe. In its Amicus Brief, the FDA characterizes its examinations of drugs as a "rigorous evaluation process [which]... scrutinizes everything about [each] drug – from the design of clinical trials to the severity of the side effects ....." (FDA Brief at 13.) As to the SSRI drugs, if the effects of the drug were indeed "scrutinized" and the evaluation process was indeed "rigorous," the agency ignored its responsibilities to protect the citizenry and did

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Advisory Committee, September 20, 1991.

[14] Transcript of Proceedings, Department of Health and Human Services, Public Health Service, Food and Drug Administration, Pharmacological Drugs Advisory Committee (hearing into antidepressant drugs and violence), September 20, 1991.

so in a big way.

After the 1991 hearings, thousands of people on SSRIs committed suicide, thousands tried and failed, thousands of persons experienced severe agitation, hostility, psychosis, liver damage, sexual dysfunction and a host of other maladies from these "safe and effective" drugs.

By the spring of 1999, over 2,000 suicides by Prozac users had been reported to the FDA's Adverse Reaction Reporting system, at least a quarter of which appeared to be linked to agitation and akathisia.[15] According to the FDA's own estimate, only about 1 percent of serious side effects are ever reported on its "adverse event system." This means that, as estimated by Dr. David Healy, Department of Psychological Medicine at the University of Wales, and one of the world's leading research psychopharmacologists has estimated that as many as 50,000 akathisia-related suicides had taken place by 1999. The total estimate for all SSRIs would of course be much larger.[16]

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[15] In 1985, German authorities had already expressed concern about Prozac causing akathisia and suicide, yet the FDA still approved the drug in 1987. In May 1985, a memo by the FDA's Safety Reviewer Richard Kapit stated, "It is fluoxetine's [Prozac] particular profile of adverse side effects which may perhaps, in the future give rise to the greatest clinical liabilities in the use of this medication to treat depression." According to Dr. David Healy (Answers.com), in 1986, there were already 10 reports of psychotic episodes, 2 reports of completed suicides, 13 attempted suicides, 4 seizures—including in a healthy volunteer.

[16] Richard DeGrandpre, "The Lilly Suicides," "Adbusters", May-June 2002.

Moreover the rash of "school shooters" over the past 15 years were almost uniformly found to have ingested SSRI medications before their incomprehensible and murderous acts were performed.[17] For example, 11 of the recent school shooters were taking these psychotropic drugs, resulting in 54 killed and 105 persons wounded.[18]

Many lawsuits have been filed against pharmaceutical companies arising out of harms alleged to have been caused by SSRI drugs in the wake of murdered

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[17] Toxicology information has not been revealed as to some of the more notorious school shooters, such as Columbine shooter Dylan Klebold. Eric Harris, the ring-leader in the 1999 Columbine school shooting at therapeutic levels of the SSRI Luvox in his system.

[18] Kip Kinkel: Maureen Sielaff, "Prozac Implicated in Oregon School Shooting," *The Vigo Examiner* 1998; Shawn Cooper: "Parents: Be leery of Zoloft study findings," *The Miami Herald*, 7 Sept. 2003; Eric Harris: "Struggling with Columbine's Questions," *CBS News.com*, 22 Oct. 2001; T.J. Solomon: Evelyn Pringle, "FDA Forgot a Few ADHD Drug Related Deaths and Injuries," *Media Monitors*, 20 Feb. 2006; Elizabeth Bush: Joyce Howard Rice, "School Shooter Took Mood-altering Drug," *The Washington Times*, 25 Mar. 2005; Jason Hoffman: "Granite Hills Gunman's Kin File Claim vs. County, Sheriff," *San Diego Union Tribune*, 2003; Cory Baadsgaard: "Fox On The Record with Greta Van Susteren," *Fox National News*, 25 Nov. 2002; Ryan Furlough: "Killer's mother urges peers to monitor depressed kids; She says anti-depressant led son to poison friend," *The Baltimore Sun*, 20 May 2004; Jon Romano: James V. Franco, "Appellate Division to Hear Two Local Landmark Cases," *The Record*, 30 Apr. 2007; Jeff Weise: "Mother of Jeff Weise Seeks to be Appointed Trustee," *WCCO-TV*, 26 Nov. 2005; Asa Coon: Scott Stephens and Rachel Dissell, "Who was Asa Coon?" *Cleveland Plain Dealer*, www.cleveland.com, 10 Oct. 2007.

family members and suicides. [19]

2. Conflicts of Interest by the Vioxx Advisory Committee

More recent deadly results from a conflicted Advisory Committee, concerned the approval of the Cox-2 pain-reliever, Vioxx. After numerous reports of deaths of Vioxx users, it was taken off the market not by the FDA, but by Wyeth – even though the FDA was well aware of the dangers, as addressed below. On February 16-18, 2005, the FDA held an Advisory Committee meeting to discuss the cardiovascular risk posed by Cox-2 inhibitors, which include Celebrex, Bextra and Vioxx, and whether they should be permitted to remain in the market. The Advisory Committee voted to keep all three drugs on the market.

The Center for Science in the Public Interest ("CSPI") thereafter evaluated the conflicts of 32 Advisory Committee members selected by the FDA to evaluate the drugs. CSPI research uncovered affiliations between 10 of the scientists that served on the committee and the three manufacturers of Cox-2 inhibitors. Another 17 scientists on the advisory committee had financial interests to other drug manufacturers. According to the New York Times,

> Ten of the 32 government drug advisers who last week endorsed continued marketing of the huge-selling pain pills Celebrex, Bextra and Vioxx have consulted in recent years for the drugs' makers, according to disclosures in medical journals

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[19] "Legal Alliance Formed to Fight Antidepressant Drug Manufacturers in Birth Defect Lawsuits," SYS-CON Media, September 10, 2007.

and other public records.

> If the 10 advisers had not cast their votes, the committee would have voted 12 to 8 that Bextra should be withdrawn and 14 to 8 that Vioxx should not return to the market. The 10 advisers with company ties voted 9 to 1 to keep Bextra on the market and 9 to 1 for Vioxx's return.[20]

Thus, the FDA knowingly selects persons for Advisory Committees who have conflicts of interest by virtue of receiving money from the drug companies whose products are being reviewed. The assertion that the FDA is unable to find panels of competent persons to advise on life and death issues of drug safety and efficacy who are not conflicted, seems highly implausible. Indeed, the SSRI and Vioxx catastrophes were avoidable, and represent a low point of responsibility and competence by the FDA, manifesting why checks and balances are needed to reduce the awful power the FDA seeks to exercise over consumer's lives, and what pharmaceutical companies seek to award the agency.

3. The FDA's Continuing Refusal to Eliminate Conflicts

The fact that the FDA has seen fit to file its own amicus brief, asserting that its judgments on safety and efficacy should not be examined, investigated or second guessed in civil litigation, itself manifests the need to permit such "second guessing."

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[20] *Ten Voters on Panel Backing Pain Pills Had Industry Ties*, New York Times, February 25, 2005.

From the late 1960's through the late 1970's, the FDA was taxpayer-funded and several Congressional committees were engaged in FDA oversight, regularly holding hearings and asking tough questions aimed at enforcement of the Food, Drug and Cosmetic Act. Now the FDA is literally paid "user fees" by pharmaceutical companies for making increasingly industry-favorable decisions. Starting in 1992 with implementation of the Prescription Drug User Fee Act (PDUFA), the influence of the pharmaceutical industry was greatly enhanced by this direct payment for FDA review. That funding has now reached over half a billion dollars, with the Department of Health and Human Services setting the total fee revenue amount requested from industry for fiscal year 2009 to be $510,665,000. Thus, with the passage of PDUFA in 1992, the FDA began looking upon the industry as its client – a very large paying client.

Issues over the FDA's utilization of persons with conflicts of interest have arisen in the context of Congressional investigations seeking to repair an agency out of control. In 2007, Congress passed a revision to the Prescription Drug User Fee Act to help ameliorate some of the problem identified herein, but over stringent lobbying by the FDA as well as pharmaceutical interests, the resulting legislation was inadequate to restore real independence to the Agency. Yet its purpose manifests a Congressional finding that our country faces a very severe problem in relying upon the FDA to make important determinations of safety and efficacy of drugs.

On August 4, 2008, the FDA made further public recognition of the lack of confidence in the integrity of its Advisory Committees, in an article published on its website, "FDA Announces Improved Policies

Regarding Transparency, Public Disclosure for Advisory Committees." [21] This supposedly new and improved policy did not call for the elimination of conflicts of interest of Advisory Committee members. It did not even improve the situation. Rather, the FDA announced rules which manifested its willingness to condone and embrace conflicts of interest:

> Today, FDA is instituting a cap of $50,000 as the maximum personal financial interest an advisor may have in all companies that may be affected by a particular meeting. If an advisor's personal financial interest is greater than $50,000, he or she will not be allowed to participate in that meeting. If less than $50,000, FDA officials may, in certain situations, grant a waiver, but will do so only if they determine that there is an essential need for the advisor's particular expertise.

Moreover, under this "improved" policy, the FDA directive states that "Disqualifying financial interests include only financial interests that are currently held... For example, if the employee has a $100,000 personal consulting contract that covers a five year period of work, he would be deemed to have a financial interest in the consulting contract of $20,000 per year," and would thus qualify to sit on an Advisory Committee.

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[21] Guidance for the Public, FDA Advisory Committee Members and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committee. It is reported at http://www.fda.gov/oc/advisory/GuidancePolicyRegs/ACWaiverCriteriaFINALGuidance080408.pdf

It is no exaggeration to say that this policy would be akin to the federal judiciary announcing that it had a new standard under which any judge would "normally" (but not always) be disqualified from ruling in a case where he had accepted over $50,000 from the plaintiff unless there was an "essential need" for that jurist's expertise. But if the judge had accepted only $45,000 in the prior year, or had accepted less than $100,000 over a 5 year period he could freely preside, and the chief judge would grant him a waiver of criminal prosecution.

C. FDA Employee Whistleblowers Have Revealed That They Were Pressured to Approve Dangerous Drugs

The information provided to the FDA by pharmaceutical companies is considered by the FDA to be a commercial secret of the manufacturer. CCHR's efforts in 1991 to gain information from the FDA regarding life threatening effects of Prozac under the Freedom of Information Act was met with recalcitrance and ultimately, a refusal to reveal the vast majority of the information provided by the manufacturer – because the manufacturer asserted a commercial trade secret privilege to shield the details concerning the effects of its drug. *Citizens Commission on Human Rights v. FDA*, 45 F.3d 1325, 1327 (9th Cir. 1995)

Similarly, although the FDA collects millions of adverse reaction reports and information on pharmaceutical products, it has done almost nothing to promulgate analyses of such information to the public. By federal law, manufacturers are required and practitioners are encouraged, to report adverse effects of medications to the FDA in the context of the FDA's Adverse Event Report

System.[22] Yet while the FDA has been given information with which to inform the public with summaries and analyses of the reported adverse effects of drugs, it declines to do so, asserting it is too busy with other matters and too poor to do its job competently. Moreover, the adverse drug reaction reports available on the FDA's website as raw data are formatted in such a way that only database programmers could make any sense out of them.

Each reporting year is comprised of seven text files that need to be married up. This works out to be over 94,000 pages of coded text for each year. Yet the FDA provides this information to the public as useless raw data. The text files would need to be put into a database that permits the information in the different files (patient age, drug used, diagnosis, adverse reactions, etc.) to be linked together, reconstructing an image of the actual MedWatch report.

However, while the FDA declines to adequately inform the public of summaries of the adverse reports of drugs, it actively prevents its own employees from revealing the dangers of drugs it evaluates, threatening and punishing those that refused to be silenced.

During the same time period that the FDA was asserting its expertise to make all necessary determinations as to the safety and efficacy of Cox-2 and SSRI drugs, a Senate Committee was investigating why the FDA was pressuring its scientists to *hide* information demonstrating the dangers of SSRI drugs. In September 2004, FDA drug analyst Dr. Andrew Mosholder testified

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[22] "Reporting Adverse Experiences to the FDA," FDA's MedWatch, http://www.fda.gov/medwatch/how.htm.

2004, FDA drug analyst Dr. Andrew Mosholder testified before a Senate Committee that he was ordered by his superiors to delete material on the risks of antidepressant drugs from records he was submitting to Congress and then to conceal the deletions.[23] Worse, Dr. Mosholder was threatened with disciplinary action if he disclosed information to Congress concerning the dangers of such drugs. *Id.*

Thereafter, when the numbers of deaths attributed to ingestion of Vioxx escalated to a national flap, the Senate also held hearings on how this drug could have been approved for market. One FDA employee who testified was analyst Dr. David Graham, the Associate Director of Science and Medicine in the FDA's Office of Drug Safety, who on November 18, 2004 noted the dangers of the drug were well known in the agency, but that pressure was placed upon him by the agency to suppress and hide his concerns. [24]

Two weeks later, hearing that *The Lancet* intended to publish Dr. Graham's research on Vioxx dangers, FDA executives took the further extraordinary step of contacting the publisher and seeking to block publication of the article. [25]

Another FDA official wrote an internal e-mail stating that the manufacturer of Vioxx, "needs to know

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[23] FDA Told Its Analyst to Censor Data on Antidepressants, *Washington Post*, September 24, 2004.

[24] Testimony of David Graham, M.D., MPH, Before Senate Finance Committee, Nov. 18, 2004.

[25] *Scientist Says FDA Called Journal to Block Vioxx Article*, USA Today, November 28, 2004.

extensive media attention that this will likely provoke."[26]

Nine months after his Congressional testimony, Dr. Graham was interviewed and said despite his revelations, nothing had changed in the agency,

> The structural problems that exist within the FDA, where the people who approve the drugs are the ones who oversee the post marketing regulation of the drug, remain unchanged. The people who approve a drug when they see that there is a safety problem with it are very reluctant to do anything about it because it will reflect badly on them. They continue to let the damage occur. America is just as at risk now, as it was in November [when the testimony was given], as it was 2 years ago, and as it was five years ago. [27]

After the incidents involving Dr. Graham and other FDA scientists who were pressured to alter findings were revealed, the non-profit Union of Concerned Scientists conducted a survey of FDA scientists published in July, 2006.[28] Citing that "[a]n unprecedented level of political

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[26] *FDA Official Alleges Pressure to Suppress Vioxx Findings*, Washington Post, October 8, 2004.

[27] *David Graham: Public Health Enemy*, Robert Goldberg, April 18, 2007, at http://www.drugwonks.com/2007/04/david_graham_public_health_enemy.html.

[28] Evidence of Political Interference: Summary of the FDA Scientist Survey, July 2006; http://www.ucsusa.org/scientific_integrity/interference/fda-scientists-survey-summary.html.

interference threatens the integrity of government science," the group sent questionnaires to nearly 6,000 FDA scientists, questioning if they had been "asked, for non-scientific reasons, to inappropriately exclude or alter technical information or conclusions in an FDA scientific document." Fifteen percent of about 1,000 scientists who responded, said they had been wrongly asked to withhold or alter information or their conclusions in agency documents. Another 17% of the respondents said they had been asked by FDA officials "to provide incomplete, inaccurate or misleading information to the public, regulated industry, media or elected/senior government officials." Another 40% said they feared retaliation if they voiced concerns about product safety in public. *Id.*

The FDA's response was that the survey was a "counter-productive exercise," according to the FDA's spokesperson, Susan Bro.[29] Perhaps it was counter-productive to the Agency's public relations, but it was revelatory that the Agency resorted to unethical and heavy-handed tactics against its own scientists who balked at approval of dangerous substances to an uneducated and trusting public.

As stated by Graham in his November 2004 testimony before Congress,

> When [the FDA] division approves a new drug, it is also saying the drug is "safe and effective." When a serious safety issue arises post-marketing, their immediate reaction is almost always one of denial,

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[29] *Some US FDA Scientists Claim Interference: Survey*, Reuters, July 21, 2006.

> so there can't possibly be anything wrong with it. The same group that approved the drug is also responsible for taking regulatory action against it post-marketing. This is an inherent conflict of interest. [30]

In testimony to Congress, Dr. Graham also noted a significant philosophical underpinning to FDA analyses and the way it treats or disregards information to protect the public: that the "FDA always claims that randomized clinical trials provide the best data." Thus, whether the "randomized trials" undertaken by the drug manufacturer are good, bad, honest or falsified, the FDA assumes the data therein is accurate, and ignores real world sources of information that are *not* "randomized trials." [31]

FDA employees other than Drs. Graham and Mosholder also refused to condone the apparent manipulation of the FDA's watchdog role. One who paid the price was FDA Veterinarian Dr. Richard Burroughs, who reviewed animal drug applications at the FDA Center for Veterinary Sciences. In 1985, Burroughs headed the FDA's safety review of the controversial genetically engineered bovine growth hormone, rBGH.

According to Dr. Burroughs, Monsanto lobbied to ease strict safety testing protocols, and dropped diseased cows from rBGH test trials to skew results. Dr. Burroughs publicly criticized the FDA's handling of rBGH to Congressional and state legislatures, and in the media.[32]

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[30] Testimony of David J. Graham, MD, MPH, November 18, 2004 Mr. Chairman and members of the Committee.

[31] Testimony of David J. Graham, MD, MPH, November 18, 2004 Mr. Chairman and members of the Committee.

[32] Linn Cohen-Cole, "The Criminalization of Raw Milk,"

publicly criticized the FDA's handling of rBGH to Congressional and state legislatures, and in the media.[32] He claimed he was prevented by his superiors from investigating data submitted by industry revealing possible health problems caused by rBGH. After several years of refusing to be silenced, in November 1989, Dr. Burroughs was fired for alleged "incompetence."[33] In a 1991 article Dr. Burroughs described a change in the FDA beginning in the mid-1980s. "There seemed to be a trend in the place toward approval at any price. It went from a university-like setting where there was independent scientific review to an atmosphere of 'approve, approve, approve.'" [34]

And, as stated by Dr. Graham, "the FDA has let the American people down, and sadly, betrayed a public trust."[35] Many more examples of such misconduct are available in the public record – far too many to address in this Amicus Brief. However, these examples demonstrate why the FDA cannot be entrusted with carte blanche authority to make binding pronouncement of safety and efficacy of drugs which may not be "second guessed" by those who may be harmed.

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[32] Linn Cohen-Cole, "The Criminalization of Raw Milk," *CounterPunch*, April 26/27, 2008; Jennifer Ferrara, "Revolving Doors: Monsanto and The Regulators," *Monitor*.

[33] *Id.*

[34] Jennifer Ferrara, *Revolving Doors: Monsanto and the Regulators* "The Ecologist", http://www.monitor.net/monitor/9904b/monsantofda.html

[35] Jennifer Ferrara, *Revolving Doors: Monsanto and the Regulators* "The Ecologist", http://www.monitor.net/monitor/9904b/monsantofda.html.

D. The FDA's Questionable and Conflicted Evaluations of Drugs Must Not Preempt the Ability Of Those Harmed from Seeking Recourse

The FDA's Amicus Brief provides little reason to trust the FDA's determination of the safety of drugs. The Agency has adopted a pharmaceutical public relations argument to justify its refusal to fully reveal the potential dangers of drugs to an unsuspecting public. The FDA's Brief states, "FDA also balances the health benefits and detriments of particular labeling, in part because labeling must strike a balance between notifying users of potential dangers and not necessarily deterring beneficial uses through overwarning." (FDA Brief at 8.) Thus, the joint position of the pharmaceutical companies and the FDA is that telling consumers too much information about the potentially deleterious effects of drugs may cause a consumer to reject them or a doctor to eschew them out of concern for harm to his patients.

In short, the FDA admits to choosing to withhold information about medications from consumers and physicians because the FDA does not want to upset consumers with the full truth about drugs they might ingest. The FDA, in its wisdom, believes it knows better than you and I about what knowledge we should have about the drugs we may take and about what knowledge our physicians really need to assist us to make such decisions. Because of this entirely theoretical possibility that someone might *not* take a drug the companies wish to sell, the FDA is withholding from us all, the country's consumers, derogatory facts about drugs because we are all too stupid, too foolish, or far too easily frightened.

sell, the FDA is withholding from us all, the country's consumers, derogatory facts about drugs because we are all too stupid, too foolish, or far too easily frightened.

On behalf of Amici's many chapters and the thousands of victims who have sought assistance from CCHR to learn the truth about drug effects, it respectfully declines the FDA's supposedly benevolent withholding of important information. The common theme of aggrieved family members of persons who committed suicide caused by pharmaceutical medications or lost their health as a "side effect," is that they simply were not told and did not know this result was possible.

The FDA fights for turf to exclude the sort of intense oversight of drug safety which could only realistically be generated by the victims of pharmaceutical products in civil litigation, who have the ability to remain focused for the years necessary to gain justice. Such intense focus is lacking in the FDA, which is willing to give responsibility for important determinations to outside "experts" who are paid by the pharmaceutical companies which sponsored the drugs at issue. Only the victims of these drugs and their legal counsel would have the staying power to counter the millions of dollars the pharmaceutical companies can muster to prevent careful scrutiny.

Viewed in the historical context of the FDA's acceptance of conflicts of interest of the persons making life and death decisions over the use of drugs, its refusal to eliminate conflicts and its suppression of adverse opinion of its own employees, the FDA's position in this case is a justification for utter malfeasance. The Agency has a public trust and is expected to be above the fray of commercial interest and to act in the best interests of

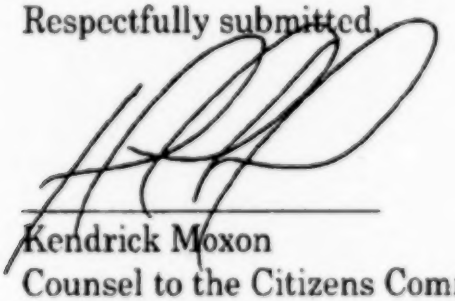
protecting consumers and saving lives. That this agency would represent it is the sole competent entity to make these important determinations on behalf of all citizens – such that its determination finally and legally *establish*,
without more, that FDA approved drugs *are* safe and effective – is a damning commentary upon our government's inability to act with integrity to provide for the health, safety and freedom of its citizens.

IV - CONCLUSION

Safety and efficacy determinations of the FDA should not be permitted to preempt the nation's citizens from seeking judicial recourse for harms caused to them by pharmaceutical companies.

Dated: August 14, 2008

Respectfully submitted,



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